

**REMARKS**

With this response, claims 32-48 are pending. Claims 32 - 37 have been amended without prejudice or disclaimer. Claims 41-43 and 47-48 have been withdrawn without prejudice or disclaimer due to the election by original presentation restriction requirement applied by the Examiner. Regardless, Applicants reserve the right to prosecute the non-elected invention in a continuing application. Support for the foregoing amendment can be found throughout the specification and the claims as originally filed, for example, in the Substitute Specification at page 10, lines 21 - 23; page 60, line 1 - page 63, line 2; page 38, line 10 - page 41, line 18; page 56, lines 2-11; page 58, line 7 - page 59, line 5; and Table 14.

Applicants would like to thank the Examiner for removing the rejection of claims 32-36 under 35 U.S.C. 112, second paragraph. Office Action mailed on January 11, 2007 at page 4 ("Final Office Action").

**I. Rejection under 35 U.S.C. § 112, First Paragraph, Scope of Enablement**

Claims 32-40, and 44-46<sup>1</sup> were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable any person skilled in the art to make and use the invention commensurate in scope with the claims. Final Office Action at page 5. Applicants disagree but appreciate and thank the Examiner for her suggested enabled claim. To facilitate prosecution, Applicants have amended the claims in conformity with the Examiner's proposed claims. As such, Applicants respectfully request that the Examiner withdraw the rejection.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

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<sup>1</sup> Claims 32-37 are all independent claims; Claim 38 is dependent on Claim 32; Claim 39 is dependent on Claim 33; Claim 40 is dependent on Claim 34; Claim 44 is dependent on Claim 35, Claim 45 is dependent on Claim 36; and Claim 46 is dependent on Claim 37

## II. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 32-40 and 44-46 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Final Office Action at pages 5-6. In support of this rejection, the Examiner alleges that the claimed invention is rejected “for reasons of record in the Office Action dated 27 July 2006.” Final Office Action at page 5. The Examiner goes on to state that “[a]pplicant’s arguments have been fully considered but have not found to be persuasive, because the brief description in the instant specification is directed to the mature full-length protein, not the entire genus of fragments or variants.” *Id.*

Applicants respectfully disagree with the Examiner’s written description rejection under 35 U.S.C. § 112, first paragraph. However, in order to facilitate prosecution, Applicants have amended claims 32-37 in conformity with the Examiner’s suggestion.

The standard for determining whether a claim drawn to a genus meets the written description requirement is clear. “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . , reduction to drawings . . . , or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.” *See Regents of the University of California v. Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; M.P.E.P § 2163(II)(3)(a)(ii) (emphasis added). A “representative number of species” means that the species which are adequately described are representative of the entire genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *Id.* Applicants have met this burden.

As set forth in *Regents of the University of California*, “an adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a

mere wish or plan for obtaining the claimed chemical invention. 119 F.3d at 1568, 43 USPQ2d at 1404. This is exactly what Applicants have provided.

The chemical sequence listing for SEQ ID NO:6 is provided in the specification. Sequence listing at pages 6-7. This alone is sufficient to indicate that the Applicants were in possession of the claimed invention at the time of filing. However, in responding to Applicants remarks of October 27, 2006, the Examiner did not address this point. Moreover, the Examiner has provided no legal or scientific basis of why the chemical sequence listing for SEQ ID NO:6 is rejected under 35 U.S.C. §112, first paragraph. In light of this, Applicants respectfully request that the Examiner withdraw the rejections or provide a legal basis of why 35 U.S.C. §112, first paragraph, is not satisfied.

The specification also describes the functional and physical properties of OCIF proteins encoded by SEQ ID NO:6. Specification at page 10, lines 12-17 and Figure 15. For example, the specification details the *in vivo* effect of OCIF on increasing the mechanical strength of bones in rats. *Id.* The specification also discloses the use of OCIF in improving decreased bone mass and increasing bone density. Specification at page 10, lines 18-20. Again, in responding to Applicants remarks of October 27, 2006, the Examiner did not address this point.

The Examiner acknowledges that the OCIF polypeptide comprising the amino acid sequence of SEQ ID NO:5 satisfies the written description requirement. Office Action mailed on July 17, 2006 at page 11 ("Office Action"). The Examiner also confirms that the OCIF protein of SEQ ID NO: 5 is encoded by SEQ ID NO:6, and that it has a role in bone absorption. Office Action at page 9. Because it is "a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it," Applicants respectfully submit that the claims would satisfy the written description requirement under 35 U.S.C. §112, first paragraph. *In re Wallach* 378 F.3d 1330, 1334 (Fed. Cir. 2004). For example, the Examiner states that OCIF comprising the amino acid sequence of SEQ ID NO:5 satisfies the written description requirement, it would necessarily be the case that a protein encoded by SEQ ID NO:6 (and encoding a protein with 100% sequence identity to the OCIF protein of SEQ ID NO:5) would also satisfy the written description requirement (for example, *see* claims 32-34).

In rejecting claims 35-37, the Examiner asserts that "hybridization details [are] not a valid limitation to claims directed to polypeptides." Final Office Action at page 6. Applicants

disagree. The Examiner has provided no legal factual basis or justification for the assertion that "hybridization details [are] not a valid limitation to claims directed to polypeptides." *Id.* In fact, claims 35-37 are directed to methods and not explicitly to polypeptides as the Examiner asserts. Irrespective of this, Applicants submit that the Examiner has not presented sufficient evidence to reject claims 35-37 under 35 U.S.C. §112, first paragraph.

Moreover, Applicants disagree with the Examiner's assertion that "even if the claims were amended such that the proteins encoded by the amino acids were identified by hybridization, they would still encompass variants with no required structural or functional characteristics and thus would still not be adequately described by the specification." Final Office Action at page 6. Applicants have provided a representative number of species combined with their shared physical properties. For example, numerous biologically active OCIF variants, including OCIF2, OCIF3, OCIF4, and OCIF5, were obtained from the cDNA library constructed with IMR-90 poly(A) + RNA using the OCIF cDNA fragment as a hybridization probe. Substitute Specification, for example, at page 8, line 24 - page 9, line 2; page 24, lines 1 - 24; page 38, line 10 - page 42, line 5. Additionally, OCIF2, OCIF3, OCIF4, and OCIF5 each have the ability to inhibit osteoclastogenesis. Substitute Specification, for example, at page 9, lines 1-2 and page 42, lines 3-5. Given this, Applicants respectfully submit that claims 35-37 satisfy 35 U.S.C. §112, first paragraph.

Applicants respectfully submit that one skilled in the art would readily appreciate that Applicants, at the time of the filing of the present application, were in possession of the claimed invention and, therefore, have met the written description requirement. As such, it is submitted that the claims comply with 35 U.S.C. §112, first paragraph, and withdrawal of this rejection is respectfully requested.

### **III. Nonstatutory Double Patenting Rejection**

The Examiner asserts that claims 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654. Final Office Action at page 7. In rejecting these claims, the Examiner asserts that "[t]he rejections of claims 32-37 are applied to

the amended claims (32-27), for reasons of record in the Office Action dated 27 July 2006.” *Id.* Applicants respectfully disagree with the Examiner.

#### Claims 32-34

Applicants respectfully submit that the Examiner has provided no evidence that claims 32-34 are obvious in view of claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654. However, in order to facilitate prosecution, Applicants are willing to consider submitting a Terminal Disclaimer in the present case with regard to U.S. Application Serial No. 10/979,654 upon an indication of allowable subject matter. Additionally, it is noted that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. *See, e.g., Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991) (“filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection”). In light of the above, Applicants respectfully request that the Examiner hold in abeyance the nonstatutory double patenting rejections over claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654.

#### Claims 35-37

Applicants respectfully disagree with the Examiner’s rejections of Claims 35 - 37 under nonstatutory obviousness-type double patenting. However, in order to facilitate prosecution, Applicants have amended claims 35-37 without prejudice or disclaimer.

Applicants respectfully submit that the Examiner has provided no legal or scientific basis whatsoever that claims 35-37 are obvious in view of claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654. The Examiner rejects claims 35-37 solely “for reasons of record in the Office Action dated July 27, 2006.” *Id.* In doing so, the Examiner has ignored the claim amendments submitted concomitant with the response to the Non-Final Office Action dated July 27, 2006. Claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654 do not refer to an OCIF protein which is encoded by a nucleic acid molecule that hybridizes with another nucleic acid molecule having SEQ ID NO:6 in a 0.5x SSC solution at 65°C. Claims 32, 33, 35, and 36

of co-pending Application No. 10/979,654 do not even use the term “hybridizes.” The Examiner has not accounted for this in rejecting the claimed invention. Applicants respectfully submit that this is enough to withdraw the obviousness-type double patenting rejection over claims 35-37.

#### **IV. Rejection under 35 U.S.C. § 112, Second Paragraph**

The Examiner asserts that claims 35-37, 44-46 are indefinite for allegedly failing to point out and distinctly claim the subject matter which applicant regards as the invention. Final Office Action at page 7. The Examiner alleges that “claims 35-37, 44-46 are vague and unclear, because the nucleic acid encoding the OCIF protein is SEQ ID NO:6, not its complement, will not be able to hybridize itself.” *Id.*

Applicants respectfully disagree with the Examiner’s indefiniteness rejection under 35 U.S.C. § 112, second paragraph. However, in order to facilitate prosecution, Applicants have amended claims 35-37 without prejudice or disclaimer. If this is not sufficient to remove this rejection, Applicants request further clarification from the Examiner.

In light of the above, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection over claims 35-37, 44-46.

**CONCLUSION**

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kristan Lansbery". The signature is written in a cursive, flowing style.

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